Pesticide Program Dialogue Committee

Transcript of Meeting on May 9 & 10, 2002
at Georgetown University Conference Center

Excerpt to Include Presentation and Discussion Concerning Section 18 Reform
on May 10, 2002

what we said would be tolerance reassessments under a theory of early noncontributors to the cumulative risk. So it's the first group of the OP tolerances that are not revoked, but are deemed by us to be reassessed. It covers 275 of the approximately 1,050, give or take -- at one time I thought it was 1066, but it turns out that's not the exact number. So it covers 275 of over a thousand OP tolerances. So you can read that at your leisure. And it demonstrates our belief that it is possible to reassess certain of the OP tolerances prior to completion of risk -- a final cumulative risk assessment and risk management. But it is based on consideration of cumulative risk as well as the individual chemical risk. So you can have that. And finally, but definitely not least, I wanted to on behalf of all of us and the committee thank Adam Sharp and Burleson Smith for the time they spent with us yesterday and for coming back and hanging out with us again today. I think it means a lot to the committee and its members, as well as to us, the career leadership in the program, to have their advice and availability, and to offer both of them a chance to say a quick hello to you before we plunge into the agenda.

MR. SHARP: All I heard was there were good discussions yesterday afternoon. I'm looking forward to hearing a little more about some of the things that got discussed yesterday, and especially this morning on the Section 18's. I guess this is the -- this is something I mentioned yesterday, and it is a very important program, of course. And I'm looking forward to hearing the discussion on the Section 18's, because I guess in my former life I know how important the Section 18 process is for all those involved. And all those involved being all those around the table and many, many folks across the country who depend on it. So I look forward to definitely hearing your remarks and taking a lot of notes. You'll see me scribbling a lot of notes. I'm a notetaker. I love to listen to what people have to say, more so than -- more so than always giving my opinion. So in that note, you'll see me taking a lot of those notes and bouncing ideas back off of you during breaks and everything else. So I look forward to working with you on this process. Thanks. Burleson?

MR. SMITH: I was going to say I really don't have any comments to make, other than I certainly found a lot of very spirited discussion yesterday. I appreciated that. I'm sorry that I missed the follow on to the biopesticide area, but I look forward to hearing more about it. The one thing I would like to say is I would be happy to make myself available, since I was not around yesterday during the follow up, to listen to any perspective you may have. I'm certainly interested in hearing more individually, and I hope to get the chance to talk with more of you during some of the break sessions today.

MS. MULKEY: Thank you. And, Jay, you can catch up on what I said about the funding.

MR. VROOM: I heard.

MS. MULKEY: Okay, good.

MR. VROOM: Three times.

MS. MULKEY: All right, great. Very good. Well, let's move then into the Section 18 reform. And Pete Caulkins is going to be our segment Chair and work us through this session.

MR. CAULKINS: Thanks, Marcia. For the next hour and 15 minutes we're going to talk about the Section 18 proposed reform. There are three of them. My panel members are Rob Forrest, who is Chief of the Minor Use, Inerts & Emergency Response Branch in the Registration Division. To my right, I have Dave Widawsky. He's Chief of the Economic Analysis Branch in the Biological & Economic Effects Analysis Division. To his right is Robin Rosenbaum. She is from the Michigan Department of Agriculture. She's the Program Manager for their Pesticide Registration Program, and she also chairs the AAPCO work group on Section 18 reforms. She will be representing sort of state perspectives on this. Bill Tracy is here as a cotton and carrot farmer in Butingwell, California. He will be representing the growers perspective. And Adam Goldberg here is going to be -- from the Consumers Union will be representing the public interest perspective on this. The format is going to be, we're going to walk through some of the most recent trends in the Section 18 program -- Rob will be doing that -- and walk through the three proposed reforms. Then I'll go to my panel members for comments, and then we'll open it for comments and questions from all of you. Rob?

MR. FORREST: Thanks. There are three proposed reforms that we're going to be discussing today. The first is renewable exemptions. Second is exemptions for resistance management. And the third is defining economic loss. And before I get into the specifics, I first want to, as Pete said, go over some of the trends that have occurred in the Section 18 program over the last six years, as well as I would like to give you some background information explaining why we're talking about these three particular reforms. When

we're dealing with the Section 18 program, I think a good place to start is to discuss volume. This graph depicts the receipts that we have had on a yearly basis for the last six years. Nineteen ninety seven was the first year of impact, I should say, coming from FQPA. Before FQPA our average receipts were about 400 to 450. After '97 they went up substantially. In '98 and '99 they hit about 600, and in 2000 they did start to decrease. Last year we ended up with about 540.

Another way to indicate volume is to talk about chemical/crop combinations. To give you an example of a chemical/crop combination, you might think about Spinosad on peas, for instance, and the multiple requests that we get for Spinosad on peas turn out to be the number of 18's for that particular year. Before FQPA our chemical/ crop combinations averaged about 160, and you can see the receipts were much higher, obviously. In '98 and '99, they hit about 220. Since '99 they have again started to decrease. We're up to about 190.

Section 18's that are granted. Although the trend does appear that we're increasing as the years go by, the percent of 18's that we grant each year remains pretty constant at about 80 to 85 percent. Denials. The percentage also has been pretty constant. About 2 to 5 percent of our receipts are actually denied. The majority of the denials are due to lack of emergencies. There is maybe 1 percent that we deny because we can't make the safety findings, and that was true also before FQPA.

This is a comparison of receipts and turnaround time. The time that we get the application and issue a decision. Historically our turnaround time, we've always shot for 50 days, and we've always felt that that was an effective time frame for us to do the assessment that we need to do and get a response back to the grower, whether that's a positive or a negative response. In 1996, the year before FQPA, we had a 53 day turnaround time. It was one of our best. That started to increase by 2000-2001. We got down to 34 days. The number of crises. I wanted to put this chart in because before FQPA, we averaged about 60. There is a good definition of crisis in the background material that you have. After FQPA -- '97, '98 and '99 -- our crises went up to about 125 a year, and there was a lot of criticism from external groups that they did go so high. And we took that very seriously. We worked very closely with the states. And in 2001 our crises was down to 59.

Just some findings that we have observed in 2001. The minor use program, 52 percent of Section 18's went to minor use crops. That's about 300 Section 18's that went to minor use crops. Twenty-two percent of the 18's were for conventional reduced risk chemicals, and 56 exemptions were eliminated for FY-02 growing season, primarily due to new uses and most of those new uses were minor use crops. This is a chart that depicts new uses versus the Section 18's that we received. There is a logic in the assumption that if new use registrations increase, then there must be a decrease in Section 18 receipts. And in 1995 and '96, where our new uses were about the same, the receipts were in the range that we would have expected, 400 to 450. However, in 2001 our new uses went up to 204, and our receipts were still relatively high, higher than we would like them to be. So from this chart, I think at least right now it's hard to make a correlation between new uses and how many Section 18's we might eliminate that particular year. So it appears that there is some progress. There has been a decrease in our turnaround time, there has been a decrease in crisis exemptions, and there has been a decrease in the number of FY-02 Section 18's due to new use registrations. And again, these were mostly minor use registrations.

So with such progress, why reform? Well, a couple of reasons. Back in 1995 there was a government wide effort to streamline regulations and EPA began to evaluate the Section 18 process. Also around the same time, we received a resolution from NASDA and AAPCO, NASDA being the National Association of State Departments of Agriculture and AAPCO is the Association of American Pesticide Control Officials. We received a letter from them. Their resolution is outlined in the background material. They supplied eight reforms that they would have liked -- that they wanted us to consider. Aside from these two being the obvious in terms of moving us forward, in terms of reforms I would say that because of the nature of Section 18's, we need to respond quickly and, again, either positively or negatively. And we're always looking for ways to improve the process and to expedite decisions, and that was one of the ways that we

got a response time down to 44 and 34 days.

With the letter from NASDA and AAPCO, we decided that in November of '96 we were going to hold a two day workshop to discuss the reforms and to solicit comments. The workshop was widely attended. It was very much of a diverse group. State lead agencies were represented, environmental public interest groups, pesticide companies and academia. The reforms back in '96 were put on the back burner for a while. Three months before the workshop, in August, FQPA was enacted, and this certainly changed the dynamic of the workshop in that we spent at least 50 percent of our time discussing the impacts of FQPA on the Section 18 program. And it was clear at the end of that workshop that the attendees thought at least at that time that it would be best for us to focus on addressing the FQPA issues, which we did. Having said that, we tried to keep the reforms somewhat in the public eye. In 1999 we put out a proposed rule setting tolerances for Section 18's, and in that rule we also solicited comments. We asked for comments on the NASDA/AAPCO recommendations. In 2001 we began to refocus on the reforms. The states did as well. AAPCO formed a task force. We met with the task force back in August to discuss the feasibility of all eight of the reforms, and at the conclusion of the meeting, these were the reforms that there was a consensus on in terms of going forward.

So the first reform is renewable exemptions. EPA authorizes a Section 18 by no longer than one year, and quarantine exemptions are for three years. This proposal is that if certain criteria are met, the agency would allow states to recertify an emergency situation up to two years following an initial authorization. Why are we doing this? Well, approximately 70 percent of our Section 18's are repeats, and given the high level of repeats, we feel that this approach would help conserve some resources. Certainly the state resources.
And how would it work? The first year the request would come in and we would do an assessment. Assuming that it's a renewable exemption, the assessment would be based on risk, which it always is -- dietary -- because we need to set a tolerance, ecological, environmental and occupational. We also have to determine progress towards registration. We also have to validate the emergency. And since this would be a renewable exemption, we would have to determine whether the emergency met certain criteria for a renewable exemption.

Possible criteria. The pest has developed resistance to alternatives and that's been documented. Alternative products aren't available due to cancellation. It might be a new pest. Documented loss of efficacy of registered alternatives. The key to these particular alternatives is, I think, predictability in that there is probably a good chance that these requests would last. The emergency would persist for two to three years. When would a renewable exemption be unlikely? A new crop. Weather related pest outbreak. That's not to say that someone wouldn't get a Section 18 because they had a lot of rain, but there is not a lot of predictability that they're going to have rain the next year. Poorly documented emergency situation. Sporadic pest outbreak. Again, there is not a lot of predictability there. Or where the alternative product is unavailable due to a supply shortage.

How would this process unfold? EPA would do their assessment, and at the end of their assessment if we conclude that this would be acceptable and we grant the exemption, this would be, again, a renewable exemption and it would be a one year exemption that could be renewed for two subsequent years pending EPA's review and approval of the state's confirmation that the emergency still persists. Again, the states would be required to recertify the emergency to EPA each subsequent year after the initial authorization. In terms of quality controls, recertification of the emergency would prompt the agency to reevaluate the situation each year. If any changes in the status of the exemption occur, if we receive new information, the agency would have to determine how that new information would impact the continued use of the exemption. We would notify the state. Let them know what the changes are and how those changes might impact the exemption.

Another quality control measure would be that if EPA receives new information at any point during the renewable exemption. We would inform the states that recertification is no longer an option. If, for

instance, in year two the state recertifies the emergency, we approve it and six months later we have new information that impacts the exemption, and the state still wants to consider that use prior to the next growing season, they would have to then submit an application and inform the agency how our particular argument is -- makes sense to them or not and how they would rebut our arguments. So that's renewable exemptions. Next is exemptions for resistance management. Currently, the agency's position is that Section 18's may only be authorized for resistance management in cases where documented pest resistance to the registered alternative has already developed and is expected to result in significant economic losses. The proposed reform is that if certain criteria are met, we would allow the issuance of an emergency exemption for an alternative to be used in conjunction with the registered pesticide, again where there is documented scientific evidence that resistance has developed to the currently registered pesticide, even though the degree of resistance may not have resulted in significant economic loss.

And how would these reforms work? As I mentioned, we would grant the exemption for the alternative in cases where there is documented evidence that shows that resistance is happening to the currently registered pesticide. Now, having said that, criteria would need to be established to provide guidance as to when a requested alternative could be granted under a Section 18 for reasons of resistance management. One example might be that the requested pesticide must be of a different chemical class, or a different mode of action from the currently registered pesticide. Specific criteria would need to be developed. We're in the process of doing that. Certainly, any ideas that you might have regarding criteria to resistance management would be most welcome.

MR. CAULKINS: Thanks, Rob. Now, Dave Widawsky is going to briefly explain the proposed reform on defining economic loss.

MR. WIDAWSKY: Thanks. Thanks, Pete. Well, the first question that we ask ourselves, and reasonably you ought to ask us, too, is why do the criteria need revision for determining significant economic loss. And I'm going to introduce three ideas about our reasons why we want to consider revising the criteria for determining significant economic loss.

The first one is the point that Rob made earlier, that the states have asked us to please think about are there ways to reduce the data burden that we currently have that is required in order to make our determination. Some of the states believe that the data that we're requiring can be onerous and can take a fair amount of time to collect, and we've been asked to reflect on whether we can responsibly make our determination of significant economic loss with less data. The second reason to consider revising the current criteria is a systematic difference in agricultural production systems that may lead to what we might call an unlevel playing field in some cases. And I'll talk about that when we talk about the limitations of the current criteria. And a third reason is that if we can actually make our reasonable determination and be responsible with less resources from the states, it's also going to require the agency to spend less resources on analyzing this data, so it would be a win/win situation for everybody involved.

So what I'm going to do, is I'm going to quickly recapitulate what are the current criteria for determining significant economic losses and what are some of the limitations of those criteria in relation to what I've just mentioned, and then talk about what we would like to propose for new data requirements, new methods for determining significant economic loss, and what some of the implications of this tiered system of data would be.

The current system for determining significant economic loss is based on normal or observed historical patterns of crop variations. What we've been asking for is for historical data. Five years of data on the production of that crop, the prices associated with that and the cost of production. And what we do with that is try to determine -- we make a determination of what the profit would -- the normal profit -- the historical pattern of profits would be.

When we look at the base line, we compare that base line to what the emergency situation would be in terms of potential losses and yield, and in addition to losses and yield, potential changes in quality from a particular pest or insect disease or weed. And then how the -- in addition to the potential revenue impacts, what cost impacts would arise from changes in pesticide costs, pesticide application costs, potential

changes in operating costs from making different -- using different equipment, or making additional applications, or changes in harvesting costs. And then we estimate the level of profits and what the difference in profits would be. If the impact of the emergency situation leads to profits that are outside that five year pattern that we have observed from the historical data, then we make a determination of significant economic loss. This has worked for us reasonably well, but there are some limitations to this method for determining significant economic loss.

The first is that, as most agricultural producers can attest, the profits don't fluctuate the same for all crops. My background is in agricultural production economics. And there is a lot of data to suggest that rain fed crops have -- because of the dependence on -- it depends on the rainfall in a given year, have profits that fluctuate much more widely -- or I shouldn't say widely. But much more substantially than crops that have a more controlled water control system like irrigated crops. And so the result of that is that the pattern of historical variation is going to be wider for rain fed crops and require the emergency situation to lead to a profit loss that is greater in order to fall outside that pattern of historical variation. And we've been asked to consider whether that is something that we want to reform or consider revising our criteria in order to take that into account. The second limitation is that the historical data may be affected by the emergency condition if we're relying on historical data and we have a Section 18 situation that has been occurring year to year. Over time we start to see impacts on profits and costs and pesticide use that is incorporating the Section 18 exemption, and it becomes more difficult to separate out the emergency condition from the base line condition when we're relying on historical data.

And third, the historical data may not be available for minor crops for five years in a lot of states. Those data can be hard to come by, and when we can get them, they're not always as well documented as we would like them to be. So what are we proposing? We're proposing to go to a tiered system of data requirements for determining significant economic loss. And the idea is that we would start off at a lower tier with a smaller data burden, and then depending on the findings at any given tier, increase the data requirements as we go -- if we can't make the determination at a lower tier. The first tier that we call tier one is yield based, and it's based on the presumption that if yield losses are high enough, then you can reasonably make a determination that significant economic losses are going to occur. If somebody is anticipating that they're going to lose 50 percent of their revenues, you don't have to get detailed -- we believe that you don't have to get detailed information on every pesticide application to realize that, hey, that's going to be a problem and we're going to realize significant economic losses.

And so that one of the challenges becomes how do you determine what the threshold would be, and that's something that we're working on, and I'll get into that in the case study I'm going to present next. But I just wanted to introduce that to you at this point. And what it does, it allows to even a threshold among crops and so you're not trying to downsize the historical variation, but we're setting the same threshold for different kinds of problem systems. In some cases, the economic loss isn't going to come from yield changes, but it may come from changes in the quality of the produce -- the fruits and vegetables. That's often the case for emergency situations. And so in that case -- in those kind of cases, we would like to be able to go to a second tier, and that considers economic loss as a percentage of gross profits.

In that case, we're taking into account the yield loss, but we're also accounting for price and quality effects on the changes in pest control costs. And we would compare an economic loss defined as total revenue plus changes in pest control costs as a percentage of gross profits, and that allows us to take those price quality effects into account, and make a determination with more data than we would need under the yield based tier, but still a lot less than we would require under the historical variation method. And then increase in the data requirements. If we're not finding significant economic loss in tier one and tier two and the application reports that there is an economic loss, we can consider a third tier which would look at economic loss as a percentage of operating profits. And that's getting us closer to the analysis that we're doing now in terms of data requirements for the current year, but it's basing the determination on the base line versus the current year without necessarily going to a historical variation method and setting some kind of a threshold or standard for what that percentage would be to come to a determination of significant

economic loss. So those are our tiers. And what we did is a case study, taking 89 Section 18's analyses that we did in the 1998-1999 season, and considering the analysis that we did under the current criteria, we are reanalyzing those data under our tiered system to see what would happen if we -- would we get different answers. Would we -- are we completely out of kilter here in proposing these.

What we did, is we estimated based on these 89 applications what would be -- what was the yield loss that was associated with it and under the current system did it lead to significant economic loss or not. We did the same calculation for tier two, economic loss as a percentage of gross profits. And then also for tier three, economic loss as a percentage of -- gross profits and then the tier three operating profits. And what we found was that there was no noticeable difference in the likelihood of determining significant economic loss. And what that told us basically is that we could use a lot less data -- and require the states to provide a lot less data -- and relieve some of our burden in making the determination and basically come up with the same likelihood of determining significant economic loss.

In a substantial number of the cases, about half the cases, where there was a finding of significant economic loss under the historical or the current method, yield data alone would have sufficed to come to that determination, and that suggests to us that there is a real potential for reducing the burden to states and the agencies for collecting and analyzing these data. Now, this was a real quick jog through our proposed changes for making significant economic loss determinations. If you want more information, we do have a -- there was a handout at the front on the proposed methodology, and we'll get a chance to talk about it more in the discussion section.

MR. CAULKINS: Thanks, Dave. Rob, do you want to do the next steps?

MR. FORREST: We're going to close with going over some next steps. What we're going to be doing is issuing a proposed Federal Register notice for public comment. We hope that that would happen in the summer of 2002. On an interim basis, we will be implementing the reforms in the 2003 growing season. This would provide us an opportunity to gain some experience, to test what works and what doesn't work. At the same time, we would be considering public comments, and we're going to pay very close attention to how these proposed reforms impact on the Section 18 process. After that, we'll gather up our experience and we'll report back to this committee and we will revise accordingly. Okay. Now, I would like to have Robin's -- one of our panel members -- presentation.

MS. ROSENBAUM: Thank you. As Peter said, I am here to talk to you about the perspective of the AAPCO Section 18 Task Force, and also the perspective of the sole Section 18 submitter for the State of Michigan, which has particular impact on this first Section 18 revised procedure recommendation. I've got a Power Point up there somewhere. Well, I'll get started. On the renewable Section 18 exemptions, we believe that EPA should allow states to recertify the emergency situation for the second or third year based upon the state's confirmation that the basis for an emergency situation continues to exist.

Most of the Section 18's that we request are due to the fact that the registered alternatives are no longer efficacious or not efficacious enough, or perhaps there has been a cancellation of a key pesticide, and the pesticide that we've requested under Section 18 is the best in the pipeline, if not the only product in the pipeline. So it's our feeling that if the product doesn't get registered during the year in which we've asked for the Section 18, then the urgent situation still exists in the subsequent year and would therefore warrant another Section 18 exemption. Another reason why we are supportive of this revised procedure is that data from the current season are difficult to obtain early. In Michigan where we have a single growing season, we harvest into October and oftentimes it takes, you know, a month or two or three perhaps for the growers and the Extension specialists to compile the data necessary to update the Section 18 for the subsequent growing season. That's not mine. I'm trying not to look at it. Okay. It just says PPDC, Robin on there. That's okay. There are only six of them.

So, anyway, what that does is it delays my ability to get the Section 18 into EPA until perhaps January or February or March, when I barely speak to anybody else in the office. All I do is have my head down working on these, and this year, 18 Section 18 exemptions.

So you can see that the timing issue is a problem, that by the time EPA gets the application -- and I had to put a plug in for EPA. I mean, they've done great in terms of streamlining their end of the process and the turnaround has been great. It's just that we can only get the applications in to them so early. And this pushes us right up against the growing season, and oftentimes the situation is that the growers don't know until the height of the pest occurrence whether or not they're going to have a Section 18 material. So that creates some obvious difficulties for the grower. If we could get the -- if we could certify the Section -- recertify that the emergency situation continues to exist and give the growers an extension of heads up earlier, we would have a lot more time for the growers to strategize their spray schedules for the summer, and there would be a lot more time for product stewardship. Our Extension specialists are out all -- you know, in their winter meetings all year, and they've sort of got their hands tied when they can't talk about whether or not the Section 18 products will be available in the subsequent growing season.

So if we could recertify in Michigan, for example, in December -- or even January -- that they're going to have the product in the upcoming growing season, then clearly that creates a much better situation, and particularly when you're talking about resistance management and development of a resistance management plan.

And the obvious one, better utilization of resources for the growers, the Extension specialists, the state lead agency and EPA. I think it would give us more time to focus on the initial applications and do perhaps a better job of putting those applications together. But we're continually being asked to do more with less and less and obviously need to prioritize our tasks. Michigan -- or the Governor just announced an early out package and told us that those of us who are left standing for the next 20 years can only rehire one in four positions. So we just lost 16 people. We get four back. That just tells you what our work environment is like.

And last but not least, on this one, of course EPA retains its authority to rescind or deny the emergency exemption for cause should additions to its risk database warrant such a decision. So there is always that fail safe. So we really feel that this is a win/win revised procedure recommendation. Resistance management. We feel EPA should support Section 18 exemptions for resistance management where there is documented scientific evidence of resistance to currently registered pesticides or valid research demonstrates the dynamic process of resistance is developing. As you know, resistance management is the process of prolonging the useful life of a pest control tool by delaying the selection of pest populations that are resistant to it. Resistance management programs are seen philosophically in the context of integrated pest management, where in IPM programs pests are held below economic injury levels by utilizing optimum combination of strategies which offer the most minimal adverse effects. To require growers to use up all of their effective pest management tools before the situation is considered an emergency as defined by Section 18 regulations seems to not be in accordance with IPM.

The future success of resistance management depends upon the continued availability of a diverse arsenal of efficacious pest management tools. The benefits of this would extend to the consuming public and to the environment as a whole through the increased availability of wholesome produce at affordable prices and reduced pesticide load to the land, water and air. And I have to throw in the Colorado potato beetle example in talking about reduced chemical load in the environment. Several years ago I put together Section 18's for use of a few products for the Colorado potato beetle. And in going through that process, we surveyed the Michigan potato growers and asked them to submit a list of the chemicals they were using to try and control this pest.

I mean, it was pretty incredible what they were doing. Basically, we saw the word cocktail on their spray list many, many times, that they were taking several insecticides and throwing them in the spray tank and hopefully some combination of those sprays were going to kill this persistent pest. So we eventually obtained the Section 18 exemption for Metaclopred and, you know, hugely reduced the pesticide load on the environment.

So while it's unrealistic to expect the emergency exemption process alone to provide the solution to the pest resistance problem, we feel that its judicious use in a proactive manner could offer a significant contribution to the resistance management effort. And lastly, significant economic loss. We feel that EPA should support the use of yield loss and/or other economic indicators instead of or in addition to the five year production cost averages for crops with a high variability. And I won't spend a lot of time on this one, since David did us such a nice job of laying it out.

But most of our Section 18 exemptions are for use on minor crops. Seventeen of the 18 I processed this year for Michigan alone were minor crops. Current agency guidance says that loss is significant only if it exceeds the normal variation of profits over a five year time frame. States and growers feel that this practice discriminations against minor use crops with high variability, because a much higher loss is required to fall outside of the normal range and it doesn't take into account a number of factors outside the control of the grower, which cause fluctuation in profits and losses and mask the emergency nature of the situation. An example of a situation that wouldn't fit the classic economic scenario is powdery mildew on watermelons. It is a serious late season disease, where the disease defoliates the vines exposing the melons to sunburn. Sun exposure turns the melons pale, almost white, resulting in a poor quality product. The yield numbers don't reflect the loss, because the grower can still harvest the sunburned melon crap. The powdery mildew stunts the plants and the melons, so the grower will feel the losses in the grade. Grower pack outs are the best way to analyze crap loss. The pack outs reveal the fluctuation crap grade as a result of the disease pressure. So basically that's it. Thank you.

MR. CAULKINS: Thank you, Robin. I'm going to ask Adam Goldberg from Consumers Union now to provide us with a public interest group perspective.

MR. GOLDBERG: Thank you. On the renewable exemptions, we certainly don't want EPA or the states to be wasting any resources. However, to us this proposal seems to be more about making it easier to get Section 18's that may or may not be warranted. It is one thing to streamline the process, but not if it takes the emphasis away from the real reason behind the Section 18 program. Our problem is that the whole idea of Section 18's is that they are for unpredictable, unusual and nonrecurring pest management emergencies. If the agency is asked to grant a two or three year Section 18 because of solid evidence showing that an emergency will exist for the next two or three years, the pest problem justifying the Section 18 seems well outside the definition of an unpredictable emergency.

If the goal of this current Section 18 reform process is to develop a new category of temporary limited registrations, let's be honest and up front about it and retain the Section 18 program as is, since it clearly does serve a vital, although too pliable, purpose. If there is a continuing need for a particular pesticide to be used on a particular crop year after year, then there is no longer an emergency use and the resources should be put into getting a permanent tolerance or registration in place. In fact, if the goal is efficient use of resources, why not speed up permanent registration for reduced risk, low exposure products and uses. If you look at the numbers that were presented, there are far too many Section 18's granted and the numbers seem to be going up every year. And there are very, very few denials, and while the denial numbers are higher in 2001 than in 1996, it's not an appreciable difference really. It's a very small number of the overall numbers of submissions. Basically from our perspective, the Section 18 process has gotten too routine and that's really a problem. EPA should tighten up the Section 18 process. Figure out a way to speed up reduced risk registrations and get on with some other pressing business.

On the resistance management exemptions, we think that this proposal makes more sense than the renewable exemptions. The agency has registered a few dozen very promising effective reduced risk and biopesticide products in the last five or so years, yet many are highly vulnerable to resistance problems because of their specific mode of action. It is a good idea, indeed essential for EPA to pull out the stops in an effort to head off resistance problems to key active ingredients. The Section 18 program can play an important, albeit a limited role in achieving this goal. Section 18's in the name of resistance management should only be approved by the agency, however, when there is solid evidence showing that both registrants and growers are doing everything they can through other means to responsibly manage resistance. Accordingly, if EPA accepts resistance management as a criterion for approval of Section 18's,

the applicant should be required to document that all other recommended proven resistance management strategies are being used to the full extent possible, and that still resistant populations are growing more common and/or levels of resistance are growing. In addition, explicit and strict resistance management language should be incorporated onto the labels approved covering resistance management driven Section 18's. Plus, the label should specify acceptable rotations of active ingredients as well as unacceptable rotations.

Finally, the significant economic loss proposal. This one is really problematic and always has been, I guess, and I think it always will be. History shows over and over that farmers seem to find a way to innovate around the sky is falling syndrome. I think part of the reason that they do, is in reality there are far more pest management alternatives than advocates of Section 18's might want to admit to. Plus, really serious major losses are typically associated with rather unique and limited combinations of soil types,

In talking to a couple of my colleagues about this particular proposal, one of them pointed out that there are a lot of people who are knowledgeable observers of what's going on, including Bob Holm, who call this the golden era of pest management. And I think that that's true. We think that too many Section 18's in the past have been justified by a need to bail out farmers who have made mistakes in their pest management systems, and we would strongly oppose granting Section 18's for any pesticides other than reduced risk and biopesticides if the major justification is the breakdown of an irresponsible, full throttle pesticide treadmill based pest management system. That's a lot to get out there. We would like to see EPA reward a commitment to IPM and penalize sloppy and disruptive levels of reliance on conventional pesticides. That would obviously address some of the problems that we're seeing, not only with economic loss, but in general. And we appreciate the fact that we're here before the PPDC discussing this, but I think we also have to discuss what kind of -- how we define acceptable alternatives when we're judging the economic impacts. And I think that's a general comment as well about how we should be proceeding on Section 18's. So I guess my overall comment is that we feel that there are far too many Section 18's granted in general. This is an emergency use situation and it should really be treated that way.

MR. CAULKINS: Adam, thank you very much. I will now turn it over to Bill Tracy to give us the growers perspective on those reforms.

MR. TRACY: Thank you, Pete. When Pete called and asked me to be on this panel, he said you have five minutes. And out west, a farmer can hardly say howdy in five minutes.

(Laughter.)

MR. TRACY: So I'm going to have some prepared comments here, because my mind tends to wander like a leppy calf in a herd of cattle if I don't keep everything focused. Incidentally, in California we have 281 commercial commodities in California and only half a dozen of those are major crops, so Section 18's are extremely important. A good farmer is known to have down field vision. We're constantly working with the vagaries of nature and we're planning ahead toward a multitude of variables, and that helps us decrease the changes of getting caught with a surprise and an unhappy banker at the end of the season.

In many instances when our fields are invaded and the conditions are perfect for the pest, a crop can be lost within an extremely short period of time. Renewable exemptions would allow for a down field vision of a planned emergency approach for a Section 18 application submitted. All the paperwork is reviewed much in advance of the possible need. It would allow for an orderly review without the rush of emergency and for proper planning by industry if a problem develops. It would avoid untimely and damaging delays of going through the application, review and approval process for an emergency before an emergency has been established. This seems best for all sides and it has worked well in California. It has been suggested and makes a lot of sense to issue multi-year approvals upon completion of the original complete review, and approval of second and third years would be left up to the respective state's review for renewal. They are the closest to the previous use patterns and problems, and if there is a need to renew, why duplicate the same process and same review each year at the state and federal levels.

On resistance management criteria, establishing significant economic loss is time consuming to prove,

especially in an emergency situation. Sometimes five year data is impossible to obtain, especially on new minor crops. Resistance management criterion points the issue in the right direction. It has to be a written plan. It stresses the introduction of reduced risk products. It limits the use of old products by seasonality and in some cases the number of applications in a year. It stresses introduction of new chemistries and new modes of action.

The overall goal is to maintain efficacy of whatever product is used with the hopes of not developing resistance by alternating use of different chemistries and modes of action. This would put more tools in the farmer's resistance management toolbox. Allowing this approach for qualifying for Section 18 would encourage the implementation of resistance management programs that in many cases are just being looked at in some areas today. Our California program has been effective and very beneficial to our industry and has served us well in working with government agencies. On a sidebar to that, I think allowance of reduced risk products to be introduced as a Section 18 certainly has merit, since they receive favorable treatment in today's review and release processes.

Establishing a new calculation for significant economic loss. Money should not always be the determining factor in economic analysis because of marketing schemes and/or market and price fluctuations. Also, yield losses must be weighed with an analysis, and is probably just as an important factor as the bottom line dollars. But don't forget. You can have a good price and a good yield, but if quality suffers -- as in my industry's case, sticky cotton -- or production costs soar -- such as pest control -- you will lose on the bottom line. And five years of data sometimes is impossible to provide. In conclusion, with a loss of use associated with FQPA, Section 18's become increasingly important. The Section 18 process has served the industry well by allowing the introduction of new chemistries and modes of action to address emergency situations prior to certain products receiving final registration. This process does not dilute the necessity and important review process, but gives opportunity for further review in real life but controlled settings. Unknown and unaddressed problems are sometimes realized in the process and are able to be corrected and/or addressed before final labels are issued and widespread use is initiated.

Now, just as a little aside and as a member of the regulated community, I'm going to ask the committee's indulgence to share with our regulators a little insight from the field. Farmers by nature have an aversion to paperwork. We view it as taking time away from our fields, and that is where a whole lot of conflict and misunderstanding comes from the regulated community and the regulators. Filling out paperwork either takes time away from our fields or something that must be done after dark and after work. Simply stated, we have a dirt oriented community regulated by paper oriented agencies. In my view, mandatory regulation would be much more palpable without mandatory paperwork. I'm going to share with you a form letter our family farm sends out. We receive about eight to 10 solicitations for surveys a week in the mail. This is one paragraph that comes from there.

It says we are drown in required county, state and federal forms, surveys, reports, records, notifications, postings, filings, permits, certificates, fees, descriptions, licenses, registrations, inventories, audits, meetings, classes, returns, validations, amendments, inspections, responses, handbooks, pamphlets, warnings, appeals and a slew of others that don't come to mind right now. It is getting difficult to find time to break away from the office to do real work. Thank you very much.

MR. CAULKINS: Thanks, Bill. By my watch, we have about 25 minutes for questions or comments.

DR. LOCKWOOD: I'm concerned by what I think I'm hearing as an excessive focus on the bottom line being dollars. I was at a speech last week where one of the speakers said money is only money. As a physician, I think that health based criteria ought to be essential in the determination of whether a Section 18 exemption ought to be granted. And I heard only the most oblique reference to anything that had to do with health in this process.

MALE SPEAKER: I thought it was an excellent panel presentation. Thank you. It was really very illuminating, and I liked a lot of the ideas. One of the points that Adam made, that I thought was very good, of course, was looking at reduced risk and biopesticides. Naturally, I think that's a great idea. The other thing from my perspective, Robin, and your counterparts in the other states, one of the problems we

are finding in the biopesticide industry is that we're not being looked at as the alternatives that are already registered products. And that has been typical. We see these coming through occasionally, and we're starting to see them after the fact. And we try to maybe do something for next year, too, but we find that the states don't always look at viable alternatives that are already registered. And I think it's incumbent on the states and the U.S. EPA to look at products that are already registered, and particularly the biopesticides.
MS. POPOWITZ: Sorry. It usually takes so much longer to get to me. I want to comment on -- sort of pull together a few of what I thought were really pertinent comments that went around the table and make a point from my perspective, which is the public health perspective.

We're very much supportive of the Section 18's. I understand emergencies. I understand farmers. I understand bugs and funguses. And clearly that's not an argument, I think, around this table that the importance of having those are required. Furthermore, as Robin pointed out, it is part of the appropriate integrated pest management system to respond to emergencies. Taking that point, though, and really integrating it into the conversation, it also goes against what -- I can't even quote Adam's sentence. But it had like a lot of chemicals used on the field chronically. And chronic low level constant chemical assault of the soil is not a long term solution, but it is the way farming is done for the most part.

We are having a huge problem right now that everybody is completely aware of, which is antibiotic use on farms, and this is chronic low level, constant in the feed and in the animal antibiotic usage. The antibiotics that have been preserved in the medical environment as our hard hitting, silver bullet, never used unless the guy is half dead type things, are being used in agriculture chronically and constantly. And they're surveying workers that work with these animals, and they're finding that they have some of these low level resistance organisms to what we consider the silver bullet biomedical solutions with antibiotics. Chemicals are no different. And so when you're using chemicals at chronic low levels constantly, that's not -- you're -- that's not in tune with what you're referring to as an integrated pest management need for a Section 18. So we're not asking for both. It's not fair to say we need Section 18's because this is part of integrated pest management, but we also need to constantly assault the soil with chemicals.It is not going to work in the long term. That's why we have so much pest resistance, and that's why we have soil plums, and that's why we have soil blowing around and burnt out soil and all sorts of other problems and health problems. So really understanding the importance of Section 18 needs to be disjointed from this repeat registration year after year after year which no longer constitutes an emergency, but actually constitutes a way of life and we need to deal with that separately.

Also, I want to stress the importance of considering as alternatives, as Robin and some other people did, but to, again, integrate that into practice to consider --

(End of Tape 4, Side A.)
MS. POPOWITZ: -- so that emergencies can be responded to and that people can sleep well at night. Not just the farmers, but all the rest of us that live around them and eat the food. Thank you.
MR. CAULKINS: Likewise. Dan?
MR. BOTTS: One quick question, first. On your survey or your case study of the threshold studies, will more than just a summary of that document be available? Because I would like to look at it just from the context of the Section 18's that we're involved in on the cost analysis that is there relative to crop site pest combinations don't always fit into, as Robin pointed out in the watermelon example, the model. The economic models that you're talking about. I would like to see the universe of actual Section 18 petitions that went into that survey, if I could, just to look -- get a crop site combination.
MALE SPEAKER: You would like to get a list of all the crop site combinations?
MR. BOTTS: Yeah, that went into the survey and if any of them were petitions that we had submitted. And I would like to ask a question of the people sitting around this table right now. I know Robin deals with Section 18's. How many other people in this room have actually written and submitted Section 18 petitions to the agency for approval? A point I would like to make. We do about the same number that Robin does through our association. We are the petitioning organization for the specialty crop industry to

the state lead agency in Florida. The issue that Jennifer brought up on discussion of alternatives, we've not submitted a petition since 1982 or '83 that didn't address every registered alternative or potential production practice associated with control of that pest. We produce our petition. It goes through a state review process. It usually takes a tremendous amount of time before it ever gets to the federal level where all of those issues are scrutinized and looked at.

I'm fully supportive of the reforms that are proposed in this thing, but I think there is a misconception about what is currently in Section 18 petitions and an understanding of what you have to look at from a public health standpoint. Those factors are reviewed not only by EPA, but at least in the case of Florida, and I know in the case of California, at the state level extremely extensively before those petitions ever go forward. I think that's one of the reasons why the denial rate is a little bit lower. And the ones that we've had kicked back for one reason or another have not been because of the review process that was done prior to getting to the agency. It was things that came to life after the petition had been submitted that led to issues around a particular crop pest combination.
So I would suggest that the direction you're headed is a great first step. I would also go back to the '96 workshop and pull out a lot of the other recommendations that came out of that stakeholder group involvement, that included more than AAPCO and the state lead agencies and putting forward a proposal, including public interest groups and other people, and look at some of those other options to pilot as well.
MR. CAULKINS: Thank you.
MS. SPAGNOLI: I'm speaking from the manufacturer's perspective. On one thing, I guess, I will agree with Adam. We, of course, support, you know, faster review and registration. However, in the situation with emergencies, oftentimes the data necessary to support the registration needs to be generated in response to that emergency. The glassy wing sharpshooter being one of the examples where a new pest, you know, erupted. There was an emergency situation and data needed to be generated to support a Section 3 registration. So you know you're going to have that emergency situation continue, so while that data can be generated and reviewed, that emergency will continue to exist.

Also from a manufacturer's perspective, we only produce a chemical that we're going to sell. You generally plan to only -- you know, nobody keeps excess inventories of chemicals. We only are going to buy raw materials and produce as much chemical as we plan to, you know, use that next season. So from that perspective, to have a more predictable process for being able to supply the growers would obviously be an advantage to manufacturers in their production planning. If there was a renewal process that they could then know that -- predict what quantities were going to be needed for a particular crop or pest for that next year, it would definitely make sure that we could provide the growers with the amount of chemical they were going to need.
MR. CAULKINS: Lori?
MS. HARDER: From a tribal perspective, we deal with Section 18 issue on the Tribal Pesticide Program Council, and some tribes are -- would like to use Section 18 because they do have production agriculture and other tribes do not. But there is a consensus amongst TPPC members that would support some kind of Section 18 reform that would be more restrictive, and a reform that would be for an emergency exemption and not for an emerging trend.

And as somebody who does monitoring, a lot of our tribal lands are at or adjacent to agricultural lands or wherever pesticides are being used, and I monitor water quality and soil and air quality and those type of media. And it gets really hard, because for a lot of new chemicals that are being used that are registered -- they've gone through the registration process -- there aren't laboratories that can analyze the media to see if it is in the environment. And so for Section 18's that aren't registered, I'm going to assume that there won't be any analytical methods for those in laboratories. So how does this really ensure environmental quality? You know, that there is no harm to the environment or that there is no persistence, and how can I take that back to the people and let them know that?
MR. CAULKINS: Larry?
MR. ELWORTH: Are you all going to answer that question? Okay.
MR. CAULKINS: It's answered.

MR. ELWORTH: Well, actually one of the things I did want to mention that didn't come up when Alan raised his concern that the agency does a review of the environmental and health impacts of these Section 18's before you grant them. It's not just -- there are criteria that you follow besides economic in determining whether you're going to grant an 18 or not.

Secondly, I do think one of the things Robin said made a great deal of sense. It doesn't make a whole lot of -- it makes a lot of sense to not wait until nothing works to decide to take some action. I think that's a smart way, both from an integrated pest management and from a regulatory point of view, to look at this alternative -- using the alternatives for resistance management. I wasn't quite clear, and maybe this isn't the right time to mention it. How are you going to explain the data requirements for the economic loss provisions? Would someone know beforehand which of the tiers they were applying for and would there be criteria guiding people for using tier or another? And you can decide if this isn't the place to describe that, but I would be interested in knowing that. It might be helpful.
MALE SPEAKER: We will make the criteria available and transparent, and if you want to talk about the details, during the break I'll be happy to.
MR. ELWORTH: Sure. Sure. Also, this FR notice? What is the nature of this FR notice? Is this -- does the agency believe that this -- this requires rulemaking? Are you making a proposed change to guidelines? What is the deal.
FEMALE SPEAKER: As we're currently envisioning them right now, it would really just be a Federal Register notice describing the -- actually a lot of what you heard the EPA panel talk about this morning. Probably filtering in, I think, a lot of the different comments that you're making. But it wouldn't actually be a rulemaking.
MS. MULKEY: We believe it can be done under the existing regulation.
MS. BRICKEY: Well, I have some comments, but I first wanted to ask a couple of questions. What is the agency's policy now about allowing a Section 18 for a pesticide that is not registered? No Section 3.
MS. MULKEY: You mean no Section 3 for the active ingredient?
MS. BRICKEY: Right.
MS. MULKEY: Or no Section 3 for that use?
MS. BRICKEY: No Section 3.
MS. MULKEY: Rob?
MR. FORREST: Are you talking about a new chemical?
MS. BRICKEY: Uh-huh. I hope so.
MR. FORREST: Okay. As far as a new chemical is concerned, we have had Section 18's on new chemicals. But we have only had Section 18's on new chemicals when we've had enough data to make the assessment that we need to make.
MS. BRICKEY: Meaning you've been able to grant a tolerance?
MR. FORREST: We have granted temporary limited tolerances, yes.
MS. BRICKEY: And how many of those have there been, approximately?
MR. FORREST: Very few. Certainly, maybe a handful, if that. If that.
MS. BRICKEY: And what about if you canceled a use on a particular crop. Have you granted subsequent Section 18's for that use?
MR. FORREST: For a different chemical?
MS. BRICKEY: No.
MR. FORREST: No.
MS. BRICKEY: For the same chemical. Let's say you have a pesticide. You cancel certain uses for a variety of reasons.
MR. FORREST: Right.
MS. BRICKEY: But not all uses.
MR. FORREST: Right. Probably -- I don't know off the top of my head, but certainly we would be suspect to go forward with an 18 where we canceled uses.
MS. BRICKEY: Do you have a policy on that?
MS. ROSENBAUM: Carolyn, the current regs that provide the framework for the Section 18 program

actually create what I would call sort of a higher hurdle. If you're talking about a pesticide for which we've had significant risk concerns, there is a public notification piece that we go through so that we actually have to issue a FR notice telling the world that we have received the request.

And if it were literally for a use that -- if it was the same use that had been canceled for risk concerns, the actual process is in fact quite a bit more elaborate. And at least in my memory, I don't remember receiving a request in such a circumstance or much less actually granting it. So there is a pretty high hurdle when you're talking about a chemical where we have identified significant risk concerns.
MS. BRICKEY:
MS. ROSENBAUM: Well, the basic policy is laid out in the existing Section 18 regulations, and it's not a flat out we will never consider it again. But it creates a process that is designed to provide opportunity for significant external participation and oversight precisely because there was some underlying reason for concern about that use.
MS. MULKEY: We couldn't grant it unless it met the statutory standard. Whatever the relevant standard was.
MS. BRICKEY: My experience in working with this program is that the feeling about how it is operated has waxed and waned at least three different times I can think of. The tightening of the program has been a result of huge numbers of Section 18's, oversight from the Hill, and whatever pressures the agency has felt to reform the program and make it better.

In this case, which would be a major loosening of the program, I don't know exactly what the pressure is, except that people feel that it is hard to provide data, which I'm sure sometime it is, and they don't like to do paperwork, which I totally understand because I don't like to do paperwork, either, and I can hardly figure most of the paperwork I do out. However, the number of days it takes to get a Section 18 are dramatically down. The number of crises exemptions are way down. And the number of denials are way down. So it's sort of hard for me to understand why we need to undertake a major reform of this program, given the fact that it seems to be working very well. And the other concern I have is that this is already a pretty fluid program, shall we say, and we're adding more and more -- we're taking some of the rigor we have in it -- assuming we have rigor -- and we're eliminating it and making it easier to get Section 18's. So another concern, I guess, that brings to bear for me is what would be the cost of making these changes? Would the program be cheaper if you did it this way because you have -- you're certifying repeat applications? You know, where is the good government angle on this.

MR FORREST: I don't think that the cost would be so much EPA's cost. I think it would be more for the states.
MS. BRICKEY: So the program would cost EPA the same, approximately?
MR. FORREST: Well, certainly there would be resources in terms of processing the Section 18's. That would save some resources for the Registration Division.
MS. BRICKEY: Have you projected those costs?
MR. FORREST: Not exactly, no.
MS. BRICKEY: I was just wondering if maybe we would save some money that we could apply to new registrations since we have a backlog there.
MS. MULKEY: It's relatively modest.
MR. FORREST: I don't think that the money -- the cost that we would be saving in terms of the processing of the Section 18's would necessarily transfer into review of new chemicals.
MS. BRICKEY: So I guess my feeling about this is if we had a fairly rigorous program, I would certainly support the notion of doing -- certifying renewals. I don't have a big problem with that, because I think mostly that is a matter of paperwork. But because we have what is a pretty lax program now and we're proposing to make it much more lax, I'm just wondering about the value of this program. You know, I guess I raised this when you had your workshop in 1996, Jim. I'm just wondering if we shouldn't just give the states these 18 exemptions when they ask for them and then evaluate what happened afterward, because I'm not sure that we're going to be doing a whole lot here to protect the public health, given the fact that the standards are going to be much lax -- more lax than they are now.

MR. CAULKINS: Bob?
MR. HOLM: Thank you, Pete. First of all, I want to compliment the panel for an excellent presentation. I've been in industry and around for 30 years, and I think that was the best clearest explanation that I've heard. And also, I guess, with the being around for a long time, it gives you a little bit of context.

I would like to remind people that back in the '80's there was a lot of complaints about Section 18's because they just seemed to be perpetual. There were Section 18's for eight or 10 years or so. I think maybe the longest one had run up to 12 or 15 years, and people were saying well, this is just a way for market entry early and to avoid the process of getting the data. I will say that I think this is dramatically changed right now. It's been noted in kind of a reference in Rob's presentation, but IR-4 this last year was involved in about 160 of those 400 some Section 18's. So we have a significant part of the program. We don't initiate the request. Obviously they come at the request of the state. But when we've got ongoing programs on those minor crops that we can provide residue data, you know, we've got a committed program. We're going to finish the work.

We have a 30 month completion schedule that we've committed to the grower community and EPA that we're going to get the work done and complete it. There is a commitment there. So there are data there. When the state requests them, we immediately submit the residue data that we have available so that EPA can make the risk assessments and the dietary risk assessments in order to judge whether that product is safe or not. I think what's missing here in some of the discussions -- and Bill, as a grower, pointed it out. Most of these uses are for minor crops. And FQPA is very hard -- boring down on taking products away -- older products -- for minor crop growers. So what does that leave growers to use? IR-4 has focused exclusively our program on reduced risk, safer chemistries and biopesticides to provide FQPA transition. So this is what we're working for. And to not allow these chemistries into the market, I think, is not participating in the FQPA transition process. I think another thing to really consider here is the fact that a lot of these newer chemistries have very specific modes of action, and the registrants are restricting their use to not more than one, or two sometimes, applications a year, which sets up resistant -- you know, it calls for resistance management strategies. And many of these minor crops only have one or two crop protection tools for any particular insect or disease.

So if you restrict it to one product and don't allow multiple products to have different modes of action in order to use resistance management, you are jeopardizing that new chemistry within two to three years of developing resistance before the product, you know, can really be used. So I think the Section 18 process is working. IR-4 is committed to supporting it, and we're committed to getting new reduced risk chemistries on the market that are safer for the environment and for human health use.
MR. CAULKINS: Thank you. Our hour and 15 minutes is up. I'm going to ask Shelley and Lori and Jay who had their cards up and that's it.
MS. MULKEY: And John.
MR. CAULKINS: And John.
MS. DAVIS: Thank you. I'm here on this committee today representing Eric Nicholson, and Eric in particular wanted to comment on this issue. And so I am presenting his comments. Eric Nicholson works for the Farmworker Union Pecoon in Oregon, and so his experience really focuses on Oregon.

From 1993 to 1999 the State of Oregon received 178 Section 18's, at least 10 of which involved approvals of the same chemical for three or more consecutive years. So we're really concerned about too much approvals of things that are not emergencies where the Section 18 begins to look like a round end of the Section 3 process.
In particular, we would like to raise the example of Encloselin, which in the late '90's received its 15th consecutive Section 18. So this is not the past history. This is a very current thing. And Encloselin in particular raises a lot of concerns for workers, because the evidence suggests that it has an anti-androgen effect, and so it does pose a significant health concern. And so in our view, it raised the problem that this was approved year after year and there was no adequate protections given on the worker side. And in that perspective, aside from our general opposition to this renewal process, we would like to see that when a

product is given a Section 18 and there are risk concerns, that there be added enforcement requirements to ensure that worker safety really is being protected.

Another thing we are really concerned about is the loosening of the criteria on economic loss. Because, again, that just seems to feed the idea that these things should be renewed year after year. So in a nutshell -- let me just raise one other thing. I am -- I'm not an eyewitness to this, so I just want to raise this in response to what Carolyn raised. And that is that it's my understanding that Vincloselen has now been subject to an agreement with the registrant to phase out uses for snap beans in a couple of years from now, and that when this agreement was reached, the issue got raised, well, what happens if we still need this as a Section 18 after the phase out. And this is a phase out, not a cancellation. But the problem that precipitated the phase out is a health problem. And it's my understanding that the EPA basically said that they would entertain a Section 18 at that time. So it is our view that the Section 18's become an around an un-registration even when there are health risks.
MR. CAULKINS: John?

JOHN: Thank you. I decided to raise mine back up after what I heard Bob say. I just wanted to touch on one little item quickly with respect to resistance management. The current approach has to do with problems that already exist, and the way it's proposed to be reformed or the rewrite is what is developing or happening. And I would just say that perhaps what you should do is write it so that it's a little more forward looking, because you know the factors that are likely to lead to resistance to develop. So that means that you could predict if it would happen. So, therefore, why not look forward, because the costs of allowing it to happen are too great. And, of course, the steps towards resistance management developing occur before you recognize them -- or before you can recognize them. Does that make sense? So take a little bit more forward approach and maybe rewrite that a little bit differently, so it's looking to the future and looking at our predicted capabilities with respect to resistance management. Does that make sense?
MS.BERGER: Okay. I had a comment and a couple of questions. First of all, it was brought up by Adam that one of the reasons Section 18's are needed is because farmers need to be bailed out because they've made bad pest management decisions. And I really take exception with that, Adam, because I think that farmers are some of the best multi taskers that I've ever seen. And we really do appreciate diversity in germ plasma. We've made mistakes in the past with disease susceptibility and that kind of thing. Diversity in germ plasma and diversity in products -- I can tell you in working at the field level that when a Section 18 goes through, it is not -- growers don't really like to have to rely on that system. It is a pain for a commodity group to have to go through the paperwork and generate that. And then when a Section 18 is granted -- and I know in California, DPR -- they generally do not submit a Section 18 package to U.S. EPA unless they are very sure it's going to go through. So the number -- because we have so few refusals at the national level, that means that anything that might have been rejected was most likely done so at the state level.

And when a Section 18 is passed, there is automatically a reduced -- I mean, excuse me -- a restricted use pesticide. So that means that there are -- there is extra reporting. They are subject to monitoring at the time of application by the local ag commissioners and so forth, and there are in fact enforcement requirements, whether it's health or whether it's environment. There might be X number of feet from waterways. There might be special protective equipment and this type of thing. So I just would -- for people that are not familiar at the field level with how a Section 18 comes about, believe me. Growers would much rather have a product that does not have these restrictions on it and has a full label. So that is really what growers want. So I just wanted to make that comment. And I just had a couple of questions. One, on these three tiers, is the data all submitted at once in these three tiers, or do you submit a tier and then come back with another tier? Is it one time or two times or three times?
MR. WIDAWSKY: The idea is that you would submit the data once, and whatever is sufficient to make the case is what you would submit if there's yield data. If you want to make a case and yield data is not sufficient to make a case, you think about the second tier. And if you make the determination before you send it to us, as you say you're screening it before then, then you may look at the data and analyze and consider them, and you may want to submit more data that would cover a tier three analysis. So it would

be one submission.
MS.BERGER: Okay.
MR. WIDAWSKY: And then whatever data would be appropriate to make a determination is what we look at.
MS.BERGER: Okay. And then finally one last question. One of the -- on the slide that talked about when would renewable exemptions be unlikely, one of the bullet points was that an alternative product was unavailable due to supply shortages. And I can see how that's maybe bad planning on the side of the registrant or the manufacturer. But I can see certain cases where this would be an emergency for a grower. Why is the grower being the one kind of punished here for bad projections on the part of a registrant?
MR. FORREST: What I was saying was that if there is an alternative that has been registered but that alternative might not be available, then we can use a Section 18 for another chemical.
MS.BERGER: But if it's not available due to a supply shortage, I mean, it's not available. I mean, so --
MS. MULKEY: He was saying you would use the Section 18 in that year.
MR. FORREST: Right. Right.
MS. MULKEY: But it wouldn't be a good candidate for a multi year.
MS.BERGER: Oh, okay. Okay.
MS. MULKEY: That was what that slide was about.
MS.BERGER: Okay.
MR. CAULKINS: Last comment.
MR. VROOM: It feels to me like there has been a lot of progress made, and like many who have already spoken, you know, I feel like a veteran who has had moments when my head was spinning, maybe even literally as well as figuratively, when we talked about Section 18's in the past. But I would, you know, vote on the side of those comments that have already been made that express appreciation for the progress that the agency is making. I may have missed it, but I didn't hear any references to USDA's involvement in this process. I assume that that's happening and I would encourage that. And I think in the next section of our discussions here on resources, it's appropriate for us to talk a little bit more about, you know, what does Section 18 cost in terms of agency resources and what can be saved. And Carolyn's point in that area, I think, is an excellent one that we ought to continue to put some focus on. The last question is, I recall -- I don't have a copy of FQPA here with me. But I believe there was a specific requirement of the agency on Section 18 process related to FQPA, and I'm not sure that we talked about, you know, specifically, you know, what those statutory requirements were and the agency's performance on that. Maybe it has already long ago been done, but I just can't remember that.
MS. MULKEY: A quick answer to that is, we were required to set up a process for setting tolerances. We did. We did it by rule. i think we finalized the rule. And we feel like we've fully implemented that.
MR. VROOM: And that's all working fine now, right?
MS. MULKEY: Uh-huh.
MR. VROOM: Okay. Sorry.
MALE SPEAKER: Can I clear up a point of information?
MS. MULKEY: Sure.
MALE SPEAKER: Was this proposal -- these three reforms were a proposal brought by AAPCO, is that right? And so to the extent there was any pressure, it was brought by the states for a variety of reasons, is that right?
FEMALE SPEAKER: (Inaudible).
MALE SPEAKER: Okay. Okay.
MS. MULKEY: Well, this -- your interest in this has presented us with a time management challenge, but in every other way has been very helpful. The lessen I learned from this is that there is still an interest in this topic, that it has not become ho hum despite the maturation of all our experience in this area. We anticipate that we will go through a proposal process, as we described. We can factor your input today into that proposal process, and we'll do so as we heard it and as it seems appropriate, including in solicitation of comments as well as in the proposal. One of the lessons I heard is that we probably have a challenge around transparency regarding the Section 18 process that we've not fully met, because I heard some perceptions from multiple sources that seemed to me not to jive completely with what we

understand to be reality. And so maybe this is also an opportunity for us to do more to reveal some of the basics and content about how the process works, and what the criteria are, and what the circumstances are, and also what our experience is as it relates, for example, to old chemistry versus new chemistry or other kinds of issues like that.

So I think we can factor all that in from your input. I want to also thank the panelists, who I thought were terrific and gave us this kind of multiple perspective which allowed us to kick off this very useful dialogue. Now, with respect to our time management problems, we're going to take our break now. We really, really must be back at five till. The next panel has a challenge because of their continued availability, at least some of the members. So during the break, we're going to sort through how we manage the next one. We have ample total time left to us. The challenge is just in what order we do things. But if we don't sit back down by five minutes till and not a minute later -- (Whereupon, a brief recess was taken.)

MS. MULKEY: -- our information may be, or at least our statement of opinions and positions may be. The timetable works and Joe has been very gracious to agree to do his conclusion of the updates in a minute after this next panel. So, Anne, if you could kick off the next panel.

MS. LINDSAY: Okay. This session we've actually got two panels. We'll start off with a panel composed of various different government officials, each of whom had some role to play in a set of, I think, unfortunate misuse occurrences from last year. That will include George LaRocca, who is a product manager in our Registration Division, and actually as product manager has responsibility for some of the chemicals that were actually involved. Van Kozak, a little bit to my farther right, who is one of our regional pesticide managers located in Dallas. He has actually also been a headquarters person and a state official, so he's got a fully rounded perspective. And Phil Benedict, who is in charge of pesticides for the State of Vermont, and again with one of the episodes that you'll hear had some direct hands on and involvement. And then Terry Troxell will complete -- from FDA will complete the government panel perspective.

After that we would move to sort of a short reaction panel that will include some reactions from Dan Botts on the grower perspective, Shelley Davis -- well, Shelley I actually expect will bring in some other aspects of misuse that we won't have heard up until that point. And you'll find at your place another background paper that I think has helped to inform some of the thoughts that Shelley is going to share with us. So you may want to take a look at that. And then Jay Vroom, when he's back, will be the wrap up for the reaction panel. And then just as we did with the last session, there will be some opportunity to go around the table and get some insights from the rest of you. Both for the future, how can we do better with these misuse incidents, and probably more importantly, how can we actually work together to prevent the occurrence of these kinds of events. So with that, I would like to hand it over --

MS. MULKEY: Just hold on a minute. I was hoping that before you started -- it's going to be hard for Jay, Dan and Shelley to react --

MS. LINDSAY: When they're not here?

MS. MULKEY: Yes. So I was hoping that getting this started would have the salutary effect of at least the three of them.

FEMALE SPEAKER: Here's Shelley. Here comes Jay.

MS. MULKEY: Okay.

FEMALE SPEAKER: Who else do we need?

MALE SPEAKER: Dan.

MS. MULKEY: Dan and Shelley. Oh, there's Shelley. All right. Well, two out of three is probably okay.

MALE SPEAKER: He has already made up his mind what he wants to say, anyway. You know Dan.

MS. MULKEY: Yeah, okay. Okay, Anne.

MS. LINDSAY: Okay. So with that, George is going to start and actually try to give you a fairly succinct

MR. LAROCCA: Thank you. Between May and September of last year, a number of EPA people, including myself, spent quite a bit of time on misuse incidents that occurred in several states throughout the country.